

Re #30  
DT  
3-14-02

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Steve Qi et al.

Title: CONTROLLED RELEASE  
FORMULATION COMPRISING  
GNRH-II

Appl. No.: 09/857,115

Filing Date: 06/01/2001

Examiner: Unassigned

Art Unit: Unassigned

PRELIMINARY AMENDMENTCommissioner for Patents  
Box New Application-  
Washington, D.C. 20231

Sir:

Prior to examination, Applicant respectfully requests that the above-identified application be amended as follows:

**IN THE SPECIFICATION:**

Please replace the following paragraphs with the following rewritten paragraphs. The changes are shown explicitly in the attached "Version with Markings to Show Changes Made."

Please replace the paragraph beginning on page 1 at line 23 with the following rewritten paragraph:

We have now found that GnRH-II has an important role in the function of a number of organs. For example, it influences osteogenesis and it modulates the proliferation of prostatic epithelial cells. Accordingly, we have considered the means by which this agent and its analogues might usefully be delivered in a clinical situation, and it is an object of the present invention to provide suitable formulations for achieving this purpose. The formulations according to the present invention rely on the use of a biodegradable polymer to hold the peptide in a depot, from which it is released into the systemic circulation at a controlled rate. These formulations comprise two key elements, the biologically active peptide and the biodegradable polymer. The biologically active peptide is a decapeptide according to the sequence (SEQ ID NO: 7).